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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,742	03/25/2004	Clive Elson	4245/2092	9666
959	7590	12/02/2005	EXAMINER	
LAHIVE & COCKFIELD, LLP.			WHITE, EVERETT NMN	
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BOSTON, MA 02109			PAPER NUMBER	

1623

DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/810,742	Applicant(s) ELSON ET AL.	
	Examiner Everett White	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
 4a) Of the above claim(s) 20-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-19, drawn to an N-acylated chitinous polymer having the formula set forth in instant Claim 1, classified in class 536, subclass 20.
 - II. Claims 42-50, drawn to a cross linked n-acylated-N,O-carboxyalkylchitosan and a pharmaceutical composition thereof, classified in class 514, subclass 55 plus.
 - III. Claims 20-23, drawn to a method for administering an agent in a subject, classified in class 514, subclass 54 plus.
 - IV. Claims 24-27 drawn to a method for treating a subject suffering from a gastrointestinal tract disorder, classified in class 514, subclass 55 plus.
 - V. Claims 28-31 drawn to a method for treating a subject suffering from a urinary tract disorder, classified in class 514, subclass 55 plus.
 - VI. Claims 32-36, drawn to a method for treating a subject suffering from reproductive tract disorder, classified in class 514, subclass 55 plus.
 - VII. Claims 37-39, drawn to a method for treating a subject suffering from cancer, classified in class 514, subclass 55 plus.
 - VIII. Claim 40, drawn to a method for treating a subject suffering from a nervous system disorder, classified in class 514, subclass 55 plus.
 - IX. Claim 41, drawn to a method for preventing surgical adhesion in a subject, classified in class 514, subclass 55 plus.
2. The inventions are distinct, each from the other because of the following reasons:

Claims 24-27 link(s) inventions V, VI, VII and VIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 24-27. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to

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examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions I and II-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and different effects because the inventions of Groups II-IX does require the present of a -C(=O)-R-CO₂Z or -C(C=O)-R-COG group linked to the chitosan compound as set forth in the invention of Group I.

Inventions II and III-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions because there is no indication in the inventions of Groups III-IX that the compounds that are administered and used for the treatments of the ailments thereof requires the use of N-acylated-N,O-carboxyalkylchitosan that are cross linked as forth in the invention of Group II.

Inventions III and IV-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions because a method for administering an agent in a subject, per se, as set forth in the invention of Group III is not description of treating a subject for a particular ailment as set forth in the inventions of Groups IV-IX.

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Each of the inventions Groups IV-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups IV-IX set forth methods of treatment of different ailments [(IV) gastrointestinal tract disorder; (V) urinary tract disorder; (VI) reproductive tract disorder; (VII) cancer; (VIII) nervous system disorder; and (IX) preventing surgical adhesion], which obviously have different modes of operation, different functions and different effects for each treatment.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, have acquired a separate status in the art because of their recognized divergent subject matter, the search required for one of the Group is not necessarily required for the other Groups, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Mr. Ralph A. Loren on November 18, 2004 a provisional election was made with traverse to prosecute the invention of Group I, Claims 1-19. Affirmation of this election must be made by applicant in replying to this Office action. Claims 20-50 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

6. The disclosure is objected to because of the following informalities: The formula

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"-C(C=O)-R-COG " which is set forth in the instant specification on page 2, lines 14, 16 and 17 is incorrectly written the first carbon atom in the formula does not contain the required number of bonds to complete the formula. This formula may have been intended to be written as " -C(=O)-R-COG " as set forth on page 4, line 23 of the instant specification. Also see this incorrectly written formula on page 4, lines 7, 9 and 10.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, lines 8, 10 and 11, the formula " -C(C=O)-R-COG " is incorrectly written because the first carbon atom in the formula does not contain the required number of bonds to complete the formula. This formula may have been intended to be written as " -C(=O)-R-COG ". See the correctly written formula on page 4, line 23 of the instant specification.

Claims 5 and 6 also set forth the incorrectly written formula " -C(C=O)-R-COG ", which should be corrected to read as " -C(=O)-R-COG ".

In Claim 7 the formula " -(CH₂)_a- " as an optional R group lacks clear antecedent basis since this formula was not set forth in Claim 1 from which Claim 7 is dependent from. The phrase "wherein R is...a is 1-8" should be changed to read - - wherein R is alkyl of the formula -(CH₂)_a-, wherein a is 1-8 - - or some other similar language.

Claim 10 as currently written lacks clear antecedent basis. The phrase "comprises one or more heteroatoms" should be change to read - - further comprises one or more heteroatoms - -. Note that the description of R in Claim 1, line 12, **uses close language to set forth variables**, which renders further additions to the R in Claim 10 improper.

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Claim 11 being drawn to a single polymer compound lacks proper antecedent basis by using the phrase "and mixtures thereof". This phrase suggests that a composition comprising 2 or more components is being claimed, which does not appear to be the case in the currently written claims.

Claims 2-4, 8, 9 and 12-19 are also rejected since these claims are dependent from the rejected claims and do not errors set forth therein.

Claim Rejections - 35 USC § 102

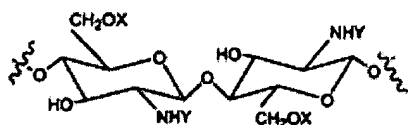
9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-8 and 11-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Elson (US Patent No. 5,888,988).

Applicants claim an N-acylated chitinous polymer, wherein said chitinous polymer is comprised of subunits of the formula:



wherein X is independently selected from hydrogen, $-(CH_2)_bCOG$, or $-(CH_2)_bCOOZ$ for each occurrence, provided that at least 10% of X groups on said polymer are $-(CH_2)_bCOOZ$ or $-(CH_2)_bCOG$; Y is independently selected from $-C(=O)-R-CO_2Z$, $-C(C=O)-R-COG$, hydrogen, carboxyalkyl, acetyl, or a pharmaceutically acceptable salt thereof for each occurrence, provided that at least 1 % of Y groups on said polymer are $-C(=O)-R-CO_2Z$ or $-C(=O)-R-COG$; R is independently selected from the group consisting of alkyl, alkenyl, and aryl; b is 1-8; G is an agent or a pharmaceutically acceptable salt thereof; and Z is hydrogen, a cation, an agent, or a pharmaceutically acceptable salt thereof. Additional limitations in the dependent claims include the N-

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acylated chitinous polymer, wherein said polymer is selected as N,O-carboxymethyl-N-succinylchitosan; the N-acylated chitinous polymer, wherein said polymer is water soluble; the N-acylated chitinous polymer, wherein said polymer is water soluble at pH's from about 1 to about 11; the N-acylated chitinous polymer, wherein Z is an agent; the N-acylated chitinous polymer, wherein said agent is a therapeutic agent; the N-acylated chitinous polymer, wherein said therapeutic agent is an anti-cancer agent; the N-acylated chitinous polymer, wherein said therapeutic agent is an agent for the treatment of a central nervous system disorder; the N-acylated chitinous polymer, wherein said therapeutic agent is an anti-inflammatory agent.

The Elson patent discloses N,O-carboxymethyl chitosan (NOCC) compounds wherein the amino groups may be linked by a bridging reagent, for example, succinic acid, to provide succinylated NOCC (see column 7, last paragraph), which is the N,O-carboxymethyl-N-succinylchitosan set forth in instant Claim 11 and anticipates the subject matter of Claim 1 when X in the formula thereof is $-(CH_2)_bCOOZ$, b is 1 and Z is hydrogen, which is representative of a carboxymethyl group; and when Y in the formula of instant Claim 1 is a $-C(=O)-R-CO_2$ group, wherein R is an alkyl or a $-(CH_2)_a-$ group, wherein a is 3, which is representative of a succinylated group. The preparation of NOCC linked with carbodiimide (EDC) and N-hydroxy-succinimide (NHS) groups is noted in Example 1 of the Elson patent. Table 1 in Example 1 of the Elson patent sets forth molar ratio of NOCC:EDC:NHS. Table 1 discloses a molar ratio for NOCC:EDC:NHS as 1:1:0.04 (see column 11), which indicates that the percent of X and Y groups present on the chitosan that are of the formula $-(CH_2)_bCOG$, or $-(CH_2)_bCOOZ$ for X and of the formula $-C(=O)-R-CO_2Z$ or $-C(=O)-R-COG$ for Y, meet the minimum requirements set forth in the instant claims. The Elson patent further discloses the NOCC group being linked to an active agent, wherein the active agent may be a peptide or protein (see column 9, line 3), which anticipates the subject matter of instant Claim 19. Also see column 9, lines 56-61, wherein the NOCC-active agent is used in methods for the prevention or minimization of infection and inflammation, debridement of wounds, topical application of active agents to wounds, absorption of exudates fluid, wound dressing and the like, which reads on the subject of Claims 15-18 wherein the

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agent thereof is a therapeutic agent, anti-cancer agent, anti-inflammatory agent or an agent for the treatment of a central nervous system disorder. The subject matter of Claims 12 and 13 regarding the solubility of the polymer in water is noted. However, this property of the polymer is not allowable over the succinylated NOCC of the Elson patent since the succinylated NOCC of the Elson patent is identical to the N-acylated chitinous polymer of the instant claims and products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ 2d 1655, 1658 (Fed. Cir. 1990), (See MPEP 2112.01). In view of the teachings of the Elson patent, the succinylated NOCC disclosed in the Elson patent anticipates the N-acylated chitinous polymer of the instant claims.

Summary

11. Claims 1-19 are rejected; Claims 20-50 are withdrawn from consideration.

Examiner's Telephone Number, Fax Number, and Other Information

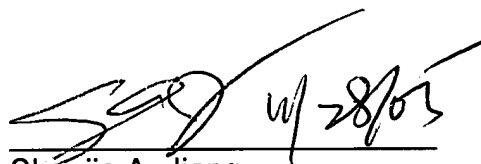
12. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang, can be reached on (571) 272-0627. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

E. White



Shaojia A. Jiang
Supervisory Primary Examiner
Technology Center 1600